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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,802	11/29/2001	James M. Wilson	GNVPN.031 USA	5849

270 7590 06/06/2003

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EXAMINER
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WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

13

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/807,802

Applicant(s)

WILSON ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,9-11,14,16-20 and 23-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6,9-11,14,16-20 and 23-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

The amendments filed on 11/29/01 and 12/31/02 have been entered.

Claims 1-6, 9-11, 14, 16-20, and 23-40 are pending.

Claims 16 and 17 will not be considered in the election/restriction because the claims depend on claims (claims 7 and 8) that were cancelled.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, 3, 4, 5, 6, 23-28, and 31-36, drawn to an isolated AAV-1 nucleic acid molecule.

Group II, claims 9 and 14, drawn to a recombinant vector comprising an AAV-1 p5 promoter having the sequence of 236 of 299 of SEQ ID NO: 1 or a functional fragment thereof.

Group III, claims 10, 29, and 37, drawn to a nucleic acid molecule encoding AAV-1 helper function, said molecule comprising an AAV rep coding region and an AAV cap coding region, wherein said cap coding region comprises at least one member selected from the group consisting of: a) vp1 of SEQ ID NO: 1, b) vp2 of SEQ ID NO: 1; and c) vp3 of SEQ ID NO: 1.

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Group IV, claims 11, 30, and 38, drawn to a nucleic acid molecule encoding AAV-1 helper function, said molecule comprising an AAV rep coding region and an AAV cap coding region, wherein said rep coding region comprises at least one member selected from the group consisting of: a) rep 78 of SEQ ID NO: 1, b) rep 68 of SEQ ID NO: 1; c) rep 52 of SEQ ID NO: 1; and d) rep 40 of SEQ ID NO: 1.

Group V, claims 18, 39 and 40, drawn to a method for AAV-mediated delivery of a transgene comprising the step of delivering to a host cell an AAV virion which comprises: a) a capsid comprising at least one capsid protein encoded by an AAV-1 cap gene.

Group VI, claims 19 and 20, drawn to a method for AAV-mediated delivery of a transgene comprising the step of delivering to a host comprising a) assaying a sample from the host to determine the presence of neutralizing antibodies specific against any serotype of AAV; and b) delivering to the host an AAV virion which comprises: i) a capsid comprising at least one capsid protein encoded by a cap gene of an AAV serotype against which the host has not antibodies as determined by a).

The inventions listed as Groups I-VI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(b) states:

“An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said

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product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

“If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.”

37 CFR 1.475(d) also states:

“If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).”

37 CFR 1.475(e) further states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.”

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In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

In addition, the technical feature linking groups I-VI appears to be that they all relate to an AAV-1 nucleic acid sequence.

However, US Patent 5,622,856 teaches that the nucleotide sequences of AAV ITR regions are known, including AAV-1 (column 5, lines 55-65). The patent further teaches using AAV-1 as a vector (column 6, lines 9-11) and an AAV p5 promoter region for AAV-1 (column 8, lines 20-24). In addition, Rutledge (J. Virol. Jan. 1998) teaches that a region from the cap gene from AAV1 is 96% identical to that of AAV-6 (page 314).

Therefore, the technical feature linking the inventions of groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be an isolated AAV-1 nucleic acid.

The special technical feature of Group II is considered to be a recombinant vector comprising an AAV-1 p5 promoter.

The special technical feature of Group III is considered to be a nucleic acid molecule encoding AAV-1 helper rep coding and an AAV cap coding region, wherein said cap coding region comprises at least one member selected from the group consisting of vp1 of SEQ ID NO: 1, vp2 of SEQ ID NO: 1, and vp3 of SEQ ID NO: 1.

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The special technical feature of Group IV is considered to be a nucleic acid molecule encoding AAV-1 helper function, said molecule comprising an AAV rep coding region and an AAV cap coding region, wherein said rep coding region comprises at least one member selected from the group consisting of: a) rep 78 of SEQ ID NO: 1, b) rep 68 of SEQ ID NO: 1; c) rep 52 of SEQ ID NO: 1 and d) rep 40 of SEQ ID NO: 1.

The special technical feature of Group V is considered to be a method for AAV-mediated delivery of a transgene comprising the step of delivering to a host cell an AAV virion which comprises: a) a capsid comprising at least one capsid protein encoded by an AAV-1 cap gene.

The special technical feature of Group VI is considered to be a method for AAV-mediated delivery of a transgene comprising the step of delivering to a host comprising a) assaying a sample from the host to determine the presence of neutralizing antibodies specific against any serotype of AAV; and b) delivering to the host an AAV virion which comprises: i) a capsid comprising at least one capsid protein encoded by a cap gene of an AAV serotype against which the host has not antibodies as determined by a).

Accordingly, Groups I-VI are not so linked by the same corresponding or a corresponding technical feature as to form a single general inventive concept.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775.

The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

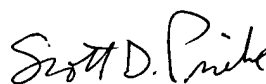
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635

  
SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER